DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#11

Re: SERZONE®
Docket No. 95E-0038

APR 18 1995

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,338,317, filed by Bristol-Myers Squibb Company, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for SERZONE®, the human drug product claimed by the patent.

The total length of the regulatory review period for SERZONE® is 4,420 days. Of this time, 3,216 days occurred during the testing phase and 1,204 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: November 17, 1982.

   FDA has verified the applicant's claim that the date the Investigational New Drug application (IND) became effective was on November 17, 1982.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: September 6, 1991.

   FDA has verified the applicant's claim that the New Drug Application (NDA) for SERZONE® (NDA 20-152) was initially submitted on September 6, 1991.

3. The date the application was approved: December 22, 1994.

   FDA has verified the applicant's claim that NDA 20-152 was approved on December 22, 1994.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Richard P. Ryan
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